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10/849,778	05/21/2004	Keisuke Inoue	P25358	1104

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EXAMINER

NWAONICHA, CHUKWUMA O

ART UNIT PAPER NUMBER

1621

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/849,778

Applicant(s)

INOUE ET AL.

Examiner

Chukwuma O. Nwaonicha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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### DETAILED ACTION

Claims 1-7 are pending in the application.

#### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss et al., {US 5,968,982}.

Applicant claims the compound of the general formula 1, its salt, ester, pharmaceutical composition and its use for treating diabetes;

Voss et al. compound differs from the instantly claimed compound in that applicants claimed compound is a subgenus of the compound of Voss et al. Specifically, applicants claim the compound of general formula 1, wherein W is

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carbonyl, n is an integer 2-9 and m is an integer 0-4 while Voss et al. teach a compound wherein the linear carbon chain is substituted with a carbonyl group.

**Finding of prima facie obviousness—rational and motivation (M.P.E.P. §2142-2143)**

The instantly claimed compound of the general formula 1, its salt, ester, pharmaceutical composition and its use for treating diabetes would have been suggested to one of ordinary skill because one of ordinary skill wishing to obtain a compound for treating diabetes is taught to select the compound from the genus of Voss et al.

One of ordinary skill in the art would have a reasonable expectation of success in practicing the instant invention by varying the substituents of the genus of Voss et al. to arrive at the instantly claimed compounds that are use for treating diabetes. Said person would have been motivated to practice the teaching of the reference cited because it demonstrates that compound of general formula 2, its salt, ester and pharmaceutical composition is useful in pharmaceutical applications, for example, for treating diabetes. The instantly claimed invention would therefore have been obvious to one of ordinary skill in the art.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected because the phrase "a protective group" is not defined in the claim. Correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specifically for treating diseases selected from the group consisting of hyperlipemia, atherosclerosis, diabetes, complications of diabetes, inflammation, and cardiopathy, does not reasonably provide enablement for "preventing" diseases selected from the group consisting of hyperlipemia, atherosclerosis, diabetes, complications of diabetes, inflammation, and cardiopathy as claimed.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The standard for determining whether the specification meets the enablement requirement is whether experimentation needed to practice the invention is undue or unreasonable. Accordingly, even though the forgoing statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be

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enabled so that any person skilled in the art can make and use the invention without undue experimentation. See M.P.E.P. § 2164.

With regard to rejection under 35 U. S. C. 112, first paragraph, the following factors have been carefully considered (*In re Wands*, 8 USPQ2d 1400; CAFC, 1988):

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

(1) **Nature of the invention.** The invention is drawn to treating or “preventing” diseases selected from the group consisting of hyperlipemia, atherosclerosis, diabetes, complications of diabetes, inflammation, and cardiopathy with compounds of formula 1.

(2) **Breadth of the Claims.** The claims are extremely broad because they lack enablement for one of ordinary skill to practice the invention. In particular, **claim 5** that read specifically “preventing” hyperlipemia, atherosclerosis, diabetes, complications of diabetes, inflammation, and cardiopathy. However, applicants have failed to exactly show how to “prevent” these diseases as claimed.

(3) **State of the Prior Art.** There is no known preventive measure with the claimed compounds. The prior art teaches the derivatives of compound of general formula 1 and their use for treating diabetes. See US 5,968,982. Therefore, the derivatives of the general formula 1 are known useful agents in a variety of pharmaceutical treatment.

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(4) **Unpredictability of the Art.** The instant case is drawn to the “prevention” of hyperlipemia, atherosclerosis, diabetes, complications of diabetes, inflammation, and cardiopathy. “Preventing” these diseases with the derivatives of compound of general formula 1 of present invention is speculative. Applicants’ claim to “preventing” these diseases with the compounds of formula 1 is doubtful and requires objective proof. In such a speculative field, more enablement by way of specific examples is necessary in order to establish the utility of a genus. In re Fisher, 166 U.S.P.Q. 18.

(5) **Amount of Guidance Provided.** Applicants have provided no guidance for using the claimed method to “prevent” diseases. For instance, applicants state that the compound is a medicine for preventing and/or therapeutic treatment of the diseases with the compounds of claim 1. However, when considering that the claims read on the “prevention” of hyperlipemia, atherosclerosis, diabetes, complications of diabetes, inflammation, and cardiopathy, it becomes critical to know how long does one administers the said compound to “prevent” these diseases. This is critical to the practice of the invention and therefore should adequately be disclosed.

(6) **Presence or Absence of Working Examples.** There are no examples of “preventing” these diseases disclosed. Applicants only disclose examples wherein compounds of formula 1 are used to treat hyperlipemia, atherosclerosis, diabetes, complications of diabetes, inflammation, and cardiopathy.

(7) **Ordinary Skill in the Art.** The ordinary skill artisan would not be able to practice the claimed invention with the current disclosure. This is a new field with no known success for the “prevention” of these diseases with compounds of formula 1.

(8) **Amount of Experimentation Necessary.** A great deal of experimentation is required. In lieu of the fact that no animal models exist which can reasonably suggest successful "prevention" of hyperlipemia, atherosclerosis, diabetes, complications of diabetes, inflammation, and cardiopathy with the compound of general formula 1, it will be necessary for an ordinary skilled artisan to have clinical data in order to practice the claimed invention.

Thus, it can safely be concluded that the instant disclosure fails to provide an enabling disclosure for "preventing" hyperlipemia, atherosclerosis, diabetes, complications of diabetes, inflammation, and cardiopathy with compounds of formula 1.

***Allowed Claim***

Claim 3 is allowable over the prior art of record.

***Reason For Allowance***

The following is an examiner's statement of reasons for allowance: applicants' claim a 2,2 dichloro-12-(4-chlorophenyl)-10-hydroxydodecanoic acid and a 2,2 dichloro-12-(4-chlorophenyl)-10-hydroxydodecanoic acid, their salts and esters. A search of the prior art failed to uncover any reference that teaches or motivates one of ordinary skill to disclose these compounds as claim by applicants. Therefore, the instantly claimed compounds their salts and eaters would therefore not have been suggested to one of ordinary skill.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is


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571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chukwuma O. Nwaonicha, Ph.D.  
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